



Monday, December 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD. 20852

9927 '99 DEC 23 P 1:14

Reference: Docket No. 97N-484S

To whom it may concern,

I have practiced in Texas as a corneal surgeon for a number of years and am distressed to hear that the Food and Drug Administration will be adding a series of questions regarding Creutzfeldt-Jakob disease (CJD) to medical screening standards for all donor corneas. This modification will significantly affect tissues currently being obtained via legislative consent.

Texas and the United States have greatly benefited by having available these young, healthy donor corneas recovered through the cooperative efforts of medical examiners. Medical examiner laws have been instrumental in helping to eliminate the waiting lists of patients in need of sight restoring corneal transplantation; and, has successfully and safely provided donor corneal tissues (in Texas) since 1977. This important legislation provides 50%-60% of the donor corneal tissues for our community.

In checking with several neuropathologists and forensic pathologists, I have not been able to link one case of transmission of CJD via corneal transplant of tissues obtained from the forensic setting. Establishing this new screening criterion carries the potential, if not inevitable, loss of younger quality corneal tissues.

I appreciate the position that the FDA has taken to develop and maintain strict medical standards and screening devices to help ensure a safe supply of donor corneal tissues. However, with the annual incidence of CJD at one case per million population (with most cases being present in patients 60 years of age or older) and the calculated risk of a prion- infected corneal donor at .005%, imposing these screening steps which will terminate this important law is unnecessary.

There is a vital necessity for the support and continued utilization of this law within the corneal transplant community. I ask that you please reconsider your position on this important matter.

Sincerely,

Richard E. Nieman
Richard E. Nieman, MD
Medical Director

Lions Eye Bank of Central Texas

LIONS EYE BANK OF
CENTRAL TEXAS

St. David's Medical Center

919 E. 32nd Street

Austin, Texas 78705

Facility: 900 E. 30th St.,

Suite 214

Phone: 512.457.0638 or

800.977.3937

Fax: 512.457.0658

Email: lebct@io.com

GLENN CRAIG

President

CHARLES PERKINS

1st Vice President

RICHARD E. NIEMAN, MD

Medical Director

SAMUEL FULCHER, MD

Regional Medical Director

ROBERT L. ROCK, MD

Corneal Consultant

GEORGE C. THORNE, JR., MD

Corneal Consultant

GARY R. RYLANDER, MD

Corneal Consultant

BESS BELIVEAUX, CEBT

Executive Director

Certified Member:



And member of the
Eye Bank Association of Texas

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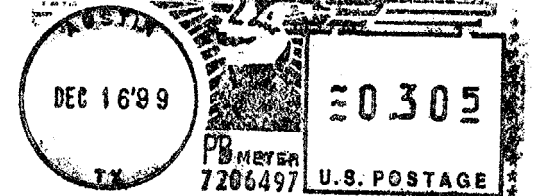
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